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DEMONT & BREYER, LLC			FRISBY, KESHA	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/807,047	FEYGIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	KESHA FRISBY	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 March 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-36 and 38 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-36 and 38 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/4/2007</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Status of Claims***

***After the amendment filed on 11/26/2007, claims 1-36 & 38 are pending. Claim 37 is cancelled and claim 38 is newly added.***

### ***Information Disclosure Statement***

1. The information disclosure statement filed 12/4/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the Foreign Document FR2622721A is not translated. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Specification***

2. The disclosure is objected to because of the following informalities: Please fill in the Statement of Related Cases in paragraph 0001 with the appropriate data.

Appropriate correction is required.

3. The disclosure is objected to because of the following informalities: The originally filed disclosure fails in the written description to include where the receiver has not offset degrees of freedom and where the axes of all of said plurality degrees of freedom of said receiver intersect one another.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 10-13, 16-20, 24-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg (U.S. Patent Number 6,654,000).**

Referring to claim 10, Rosenberg discloses an end effector (lapascopic tool 18); and a movable member (object (shaft) receiving portion 44), wherein: said end effector reversibly couples to said movable member to simulate a vascular access procedure (Figs. 1-5); and said movable member moves along a linear path (in-and-out) in response to manipulation of said end effector (column 4 lines 27-30 & column 10 lines 53-67).

Referring to claim 11, Rosenberg discloses wherein said movable member is coupled to a cable (cable 30).

Referring to claim 12, Rosenberg discloses wherein said cable (wire) is coupled to a motor (wheel and Figs 1 & 2).

Referring to claim 13, Rosenberg discloses wherein, responsive to a control signal, said motor generates a resistance to movement of said movable member (column 7 lines 35-38).

Referring to claim 16, Rosenberg discloses wherein said movable member comprises a magnet (column 8 lines 25-31), and wherein said end effector couples to said movable member via said magnet (Fig. 2).

Referring to claim 17, Rosenberg discloses further comprising a housing (gimbal apparatus 25), wherein said movable member is disposed within said housing and said end effector is disposed outside of said housing (Figs. 1-5).

Referring to claim 18, Rosenberg discloses further comprising pseudo skin, wherein said pseudo skin is substantially co-planar with a surface of said housing (Fig. 1).

Referring to claim 19, Rosenberg discloses a frame (gimbal apparatus 25); an arrangement for providing two orthogonal axes of rotation ( $A_1$  &  $A_3$ ) for said frame, wherein said frame is coupled to said arrangement (Fig. 5); and a movable member (object (shaft) receiving portion 44), wherein: said movable member receives an end effector during a vascular access procedure (Figs. 1-5); said movable member moves along a linear path in a region defined by said frame (Figs. 2A & 5: t & column 9 lines 42-45); and said linear path intersects said two orthogonal axes of rotation of said frame (Fig. 5).

Referring to claim 20, Rosenberg discloses further comprising a force-feedback assembly (column 2 lines 38-41), wherein said force-feedback assembly is coupled to said movable member (column 2 line 28 – column 3 line 20), and wherein said force-feedback assembly imparts a force that resists forward motion of said movable member by said end effector (column 2 lines 38-41).

Referring to claim 24, Rosenberg discloses pseudo skin (column 5 lines 41 & 42); and a

receiver (object (shaft) receiving portion 44) for coupling to an end effector (laparoscopic tool 18), wherein: said receiver is disposed beneath said pseudo skin (Fig. 1 & the associated text); and said receiver has no offset degrees of freedom (Fig. 6).

Referring to claim 25, Rosenberg discloses wherein a magnetic force (column 8 lines 25-31) is used for coupling said end effector to said receiver .

Referring to claim 26, Rosenberg discloses wherein said end effector is selected from the group consisting of a catheter, a needle, and a combined catheter and needle (column 7 lines 27-32 & catheter 67).

Referring to claim 27, Rosenberg discloses wherein said receiver has three degrees of freedom (column 2 lines 42-62).

Referring to claim 28, Rosenberg discloses wherein two of said three degrees of freedom are rotational ( $A_1$  &  $A_2$ ) and one of said three degrees of freedom is translational ( $A_0$ ).

Referring to claim 29, Rosenberg discloses wherein said receiver comprises a movable member (column 13 lines 42-46), and wherein said movable member is movable along a linear path (in-and-out).

Referring to claim 30, Rosenberg discloses wherein said receiver comprises a movable member (column 13 lines 42-46), and wherein said movable member is physically adapted for rolling contact during movement (column 11 lines 29-46 & Figs. 1 & 2).

Referring to claim 31, Rosenberg discloses wherein said receiver is gravitationally balanced (gravity holds receiver in position).

Referring to claim 32, Rosenberg discloses further comprising said end effector, wherein, until coupled to said receiver by a user, said end effector is disposed above said pseudo skin (column 12 lines 60-65).

Referring to claim 33, Rosenberg discloses wherein said receiver further comprises: a movable member, wherein said movable member couples to said end effector (Figs. 1-5); and a force-feedback assembly, wherein said force-feedback assembly is coupled to said movable element (column 2 lines 38-41).

Referring to claim 34, Rosenberg discloses pseudo skin (column 5 lines 41 & 42); and a receiver (gimbal apparatus) for coupling to an end effector (laparoscopic toll 18), wherein: said receiver is disposed beneath said pseudo skin (Fig. 1 & the associated text); and said receiver comprises a force-feedback assembly (column 2 lines 38-41).

Referring to claim 35, Rosenberg discloses wherein said receiver further comprises a movable member (object (shaft) receiving portion 44), and wherein: said movable member is coupled to said force-feedback assembly (column 2 line 28 - column 3 line 20); said movable member couples to said end effector (Figs. 1-5); when said movable member is coupled to said end effector, movement of said end effector causes said movable member to move (Figs. 3-5).

Referring to claim 36, Rosenberg discloses further comprising a data processing system, wherein, responsive to a signal from said data processing system (column 10 lines 22-24), said force-feedback assembly generates a force that opposes movement of said movable member and said end effector, in at least a first direction (column 2 lines 38-41).

Referring to claim 38, Rosenberg discloses said receiver (object (shaft) receiving portion 44) receives an end effector (laparoscopic tool 18), wherein said end effector removably couples to said receiver during simulation of said vascular access procedure (Figs. 1-5); said receiver has plural degrees of freedom (two, three or four degrees of freedom); and axes of all said plural degrees of freedom of said receiver intersect one another (Fig. 6).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**7. Claims 1-4 & 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (U.S. Patent Number 6,470,302).**

Referring to claim 1, Cunningham et al. discloses an apparatus comprising a receiver wherein: said receiver (shaft 44) has at least three degrees of freedom (translation, pitch & yaw), wherein axes of said three degrees of freedom intersect (claim 5); and said receiver receives an end effector (catheter 47), wherein said end effector removably couples to said receiver (Fig. 4 & the associated text). *Cunningham et al. does not explicitly state that the axes of said three degrees of freedom intersect.* Cunningham et al. does state where the axes of at least two degrees of freedom intersect (claim 5). Therefore, at least two degrees of freedom includes two or more degrees of freedom. As a result, at least two includes three. For that reason,

Cunningham et al. discloses at least three degrees of freedom.

Referring to claim 2, Cunningham et al. discloses further comprising said end effector, wherein said end effector comprises a catheter (catheter needle assembly 47).

Referring to claim 3, Cunningham et al. discloses wherein two of said three degrees of freedom are rotational (yaw & pitch) and one of said three degrees of freedom is translational (translation).

Referring to claim 4, Cunningham et al. discloses further comprising pseudo skin (36), wherein said receiver is disposed beneath said pseudo skin (From looking at Fig. 3, the shaft 44 appears to be below/within the case 32).

Referring to claim 6, Cunningham et al. discloses further comprising: a plurality of sensors, wherein said sensors: monitor movement of said receiver with respect to said degrees of freedom, wherein said movement is indicative of the position and orientation of said end effector; and generate signals indicative of said monitored movement; and a data processing system, wherein said data processing system receives signals generated by said sensors (column 4 lines 50-54).

Referring to claim 7, Cunningham et al. discloses further wherein said data processing system determines a position and orientation of said end effector based on said received signals (Fig. 1 & column 6 line 45 – column 7 line 35).

Referring to claim 8, Cunningham et al. discloses wherein said receiver comprises a force-feedback assembly (force feedback unit 54), wherein said force-feedback assembly generates a resistance to movement of said end effector (column 10 lines 3-46).

Referring to claim 9, Cunningham et al. discloses wherein said force-feedback assembly comprises a motor (column 10 lines 23-26).

**8. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. in view of Rosenberg.**

Referring to claim 5, Cunningham et al. discloses the apparatus of claim 4.

Cunningham et al. does not disclose further comprising said end effector (catheter 47), wherein said pseudo skin (4) lies between said end effector and said receiver, and wherein to simulate a vascular access procedure, said end effector is inserted through an opening in said pseudo skin to couple with said receiver. However, Rosenberg teaches further comprising said end effector (laparoscopic tool 18), wherein said pseudo skin (barrier 22) lies between said end effector and said receiver (object (shaft) receiving portion (Fig. 1), and wherein to simulate a vascular access procedure (Figs. 1-5), said end effector is inserted through an opening in said pseudo skin to couple with said receiver (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include additional limitations in regards to the effector, as disclosed by Rosenberg, incorporated into Cunningham et al. in order to simulated a laparoscopic medical procedure.

**9. Claims 14, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg in view of Cunningham et al..**

Referring to claim 14, Rosenberg discloses the apparatus of claim 11. Rosenberg does not disclose further comprising a plurality of pulleys disposed on a frame, wherein: said pulleys engage said cable; and said pulleys are arranged so that a tension in said cable

*aligns with said linear path along which said movable member.* Rosenberg does disclose wheels (column 7 lines 29-39), which are pulleys without a rope or cable. However, Cunningham et al. teaches further comprising a plurality of pulleys (pulleys 100, 112 & 115) disposed on a frame (skin traction mechanism 36), wherein: said pulleys engage said cable (belt 108); and said pulleys are arranged so that a tension in said cable aligns with said linear path along which said movable member moves (Fig. 7 & the associated text). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include pulleys, as disclosed by Cunningham et al. incorporated into Rosenberg in order to apply force or tension.

Referring to claim 15, Rosenberg discloses the apparatus of claim 11. *Rosenberg does not disclose wherein said movable member comprises a pulley, wherein said movable member is coupled to said cable via said pulley.* Rosenberg does disclose wheels (column 7 lines 29-39), which are pulleys without a rope or cable. However, Cunningham et al. discloses wherein said movable member (friction wheels 84 & 85) comprises a pulley (pulleys 100, 112, 114), wherein said movable member is coupled to said cable (belt 108) via said pulley (pulleys 112 & 114). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include pulleys, as disclosed by Cunningham et al. incorporated into Rosenberg in order to apply force or tension.

Referring to claims 21-23, Rosenberg discloses the apparatus of claim 20. *Rosenberg does not disclose wherein said force-feedback assembly comprises: a motor and a cable, wherein said cable is coupled to said motor (claim 21), wherein said movable*

*member includes a rolling-contact element, wherein said cable is coupled to said rolling-contact element (claim 22), further comprising a counterbalance, wherein said counterbalance is coupled to said frame (claim 23).* However, Cunningham et al. teaches wherein said force-feedback assembly comprises: a motor (electric motor); and a cable (offset pulley holds a rope or cable), wherein said cable is coupled to said motor (column 10 lines 21-26) (claim 21), wherein said movable member (Friction wheels 84 & 85) includes a rolling-contact element (pulleys 100, 112, 115 holds a rope or cable), wherein said cable is coupled to said rolling-contact element (Figs. 4, 5B & the associated text) (claim 22), and further comprising a counterbalance (housing 50), wherein said counterbalance is coupled to said frame (outside of shaft 44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the specifics of the force feedback assembly, as disclosed by Cunningham et al., incorporated into Rosenberg in order to apply force of a medical procedure being performed in a virtual reality simulation.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-36 & 38 are have been considered but are moot in view of the new ground(s) of rejection.

***Citation of Pertinent Prior Art***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Alexander et al. (U.S. Publication Number 2004/0076940) teaches an interface device and method for interfacing instruments to medical procedure simulation systems.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KESHA FRISBY whose telephone number is (571)272-8774. The examiner can normally be reached on Monday-Friday 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. F./  
Examiner, Art Unit 3714

/Ronald Laneau/

Supervisory Patent Examiner, Art Unit 3714

02/16/08